K042276

SEP 2 3 2004

Dräger medical
A Dräger and Siemens Company

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: D-Vapor

Common Name: Anesthesia Vaporizer

Classification Name: Anesthetic Vaporizer

Product Codes: 73 CAD

Device Class: Class II

Manufacturer: Draeger Medical AG & Co KGaA
53/55 Moislinger Allee
Luebeck, Germany

Establishment Registration Number: 9611500

Devices to which substantial equivalence is claimed:

Vapor 2000	K971923
Tec 6 Plus	K000275

Device Description:

The D-Vapor is an electronic calibrated vaporizer designed to enrich the fresh gas flow of an anesthesia delivery system with a controlled amount of Desflurane anesthetic vapor in concentrations of 2 to 18 vol.%.

Indications for Use:

The D-Vapor is an electronic calibrated vaporizer designed to enrich the fresh gas flow of an anesthesia delivery system with a controlled amount of anesthetic vapor. The D-Vapor is intended for use with Desflurane. It is not intended for use with Enflurane, Halothane, Isoflurane, or Sevoflurane or for use in a breathing circuit. Federal law restricts this device to sale by or on the order of a physician.

Intended Use:

The D-Vapor is intended to be used with Desflurane anesthetic agent, and inserted in the fresh-gas line of an anesthesia delivery system. It is not intended for use with Enflurane, Halothane, Isoflurane, or Sevoflurane, or in a breathing system.

Draeger Medical, Inc.
3135 Quarry Road
Telford, PA 18969
Tel: 215-721-5400, ext. 2363
Toll-free: 800-4DRAGER (437-2437)
Fax: 215-721-5412
E-mail: wwwinfo@draegermed.com

http://www.draeger-medical.com

Substantial Equivalence:

Like the Tec 6 Plus, the D-Vapor is an electronic vaporizer which delivers desflurane anesthetic agent. The D-Vapor can be adjusted from 2- 18 Vol.%, while the Tec 6 Plus adjustment is 1-18 Vol.%. Both the D-Vapor and the Tec 6 Plus have front display panels which provide the user with a visual indication of the status of the vaporizer for the following
categories: Operational, No Output, Low Agent Level, Warm Up, and Battery Status. Both systems also provide audible alarms, and the ability to silence alarms. Like the Vapor 2000, the D-Vapor provides a sight glass on the front of the device to visually indicate the level of agent in the vaporizer both for filling the vaporizer and monitoring remaining agent within the vaporizer.

The D-Vapor can be used with quick connect systems identical to the Vapor 2000 plug in adapter system, or identical to the Tec 6 plug in system for Selectatec® plug in connectors. It can be permanently installed using a block connector with o-rings and screws like the Tec 6 Plus, or used with conical fittings like the Vapor 2000.

The D-Vapor and the Tec 6 Plus have keyed filling systems to only allow the use of Desflurane bottles with the Saf-T-Fill™ system when adding Desflurane agent to the vaporizers.

The D-Vapor and the Vapor 2000 have a transport mode allowing the vaporizer to be removed from the delivery system and moved with agent in the vaporizer.

Both the D-Vapor and the Tec 6 Plus are contraindicated for use in an MRI environment.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2004

Ms. Gale E. Winarsky
Regulatory Affairs Project Manager
Dräegar Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K042276
Trade/Device Name: D-Vapor
Regulation Number: 21 CFR 868.5880
Regulation Name: Anesthetic Vaporizer
Regulatory Class: II
Product Code: CAD
Dated: August 20, 2004
Received: August 23, 2004

Dear Ms. Winarsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042276

Device Name: D-Vapor

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042276